REMARKS

Claims 1-5, 8-17, 37-49, and 63-81 constitute the pending claims in the present application, prior to Amendment. Claims 1, 16 and 37 have been amended to further clarify that the ultrasonic energy is delivered from a non-contact distance from the tissue and the medicament. Support for the amendment can be found, for example, in paragraph [0076] of the published application. No new matter has been added.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

Rejections

35 U.S.C. 103(a)

Claims 1-5, 8-12, 14-17, 37-42, 47-49, 63-77 and 80-81 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Kost (US 6,041,253) in view of Gerasimenk (SU 1106485 A) further in view of Duarte (US 6,273,864). Applicants respectfully traverse this rejection.

The criteria for establishing a *prima facie* case of obviousness are detailed in MPEP 2142-2143. To establish a *prima facie* case of obviousness for combining prior art reference teachings to arrive at the claimed invention, the following three criteria must be met. The prior art references must teach or suggest each and every limitation of the claimed invention. There must be a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Finally, there must be a finding that there was reasonable expectation of success. The combination of Kost, Gerasimenk and Duarte fail to satisfy these criteria, and thus fail to undermine the patentability of the claimed invention.

None of Kost, Gerasimenk and Duarte teach or suggest delivering ultrasonic energy from a non-contact distance from the tissue *and the medicament* that is applied to the tissue to the medicament applied to the tissue and the tissue, as required by the claims. Duarte provides methods and devices for delivering ultrasound via direct contact. As such, Duarte is irrelevant to the presently claimed invention and cannot be used to overcome the deficiencies of Kost and Gerasimenk. One of skill in the art would have neither the motivation nor the reasonable

expectation of successfully combining these references to arrive at the claimed invention because of the technical and physiological differences between applying ultrasound via direct contact with tissue (as taught by Duarte) and applying ultrasound at a non-contact distance (as taught in the present application). Furthermore, if the Duarte, Kost and Gerasimenk references were (inappropriately) combined, the combination still fails to teach each and every limitation of the claimed invention. Kost describes a method where ultrasonic energy is *not* applied at a non-contact distance from the medicament. The passage cited by the Examiner (column 13, lines 26-33) must be read in context with part A of Example 1, at column 12, lines 40-62. These passages teach that the ultrasound probe was inserted into a compartment containing a buffer solution and the medicament, which in turn directly contacts the skin. Gerasimenk fails to overcome these deficiencies. As such, Applicants submit that the cited references fail to undermine the patentability of the claimed invention for, at least, failing to teach or suggest each and every limitation of the claimed invention.

Applicants have thus shown why the claimed invention is not obvious over the cited references. The cited references do not teach each and every limitation of the claimed invention. Accordingly, reconsideration and withdrawal of this rejection are requested.

Claims 43-46 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Kost in view of Gerasimenk in view of Duarte, and further in view of Martin (US 6,500,133). Applicants traverse this rejection and contend that the rejection is moot in view of the amended claims.

Applicants' arguments above with respect to the rejection in view of Kost, Gerasimenk and Duarte are equally applicable to this grounds of rejection. Martin fails to overcome the deficiencies of Kost, Gerasimenk and Duarte. Thus, regardless of whether Martin teaches the delivery of ultrasonic energy having a particular frequency or wavelength and using a radiation surface of a particular size and shape, the combined teachings of the cited references fail to teach or suggest each and every limitation of the claimed invention. If an independent claim, for example claim 1, is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Reconsideration and withdrawal of this rejection are requested.

Claims 1-4, 9-17, 63, 66, 68, 70, 71, 73, 75, 77, 79 and 81 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Henley (US 6,458,109) in view of Manna (US 5,516,043) in view of Duarte. Applicants traverse this rejection and contend that the rejection is moot in view of the amended claims.

The criteria for establishing a *prima facie* case of obviousness are detailed in MPEP 2142-2143. To establish a *prima facie* case of obviousness for combining prior art reference teachings to arrive at the claimed invention, the following three criteria must be met. The prior art references must teach or suggest each and every limitation of the claimed invention. There must be a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Finally, there must be a finding that there was reasonable expectation of success. The combination of Henley, Manna and Duarte fail to satisfy these criteria, and thus fail to undermine the patentability of the claimed invention.

One of ordinary skill in the art would have had no reasonable expectation of success in combining the teachings of the cited art to arrive at the claimed invention. Henley disclosed a wound treatment apparatus comprising, *inter alia*, a bandage to seal the wound and a nebulizer. The nebulizer relies on a flow of gas to carry the droplets from in the nebulizer to the wound area (see Figs. 2 and 3, along with column 5, lines 45-58 and column 6, line 60 through column 7, line 55). The present invention clearly teaches that the gas flow significantly reduces the efficiency of the ultrasonic energy (paragraphs [0004] and [0048]). Accordingly, even if the ultrasonic atomizer taught by Manna were used in apparatus of Henley, one of ordinary skill in the art would not have expected that this combination would meet the claim element "ultrasonic energy . . . has intensity capable of penetrating the tissue to a beneficial depth to provide a therapeutic effect to the tissue," which is present in each independent claim. The teachings of Duarte would not have changed the expectations of one of ordinary skill. As discussed above, Duarte is directed to a contact method of applying ultrasonic energy and cannot be combined with the other cited references. Thus, absent a reasonable expectation of success, the claimed invention cannot be obvious over the cited references.

Applicants have thus shown why the claimed invention is not obvious over the cited references. One of ordinary skill in the art would have had no reasonable expectation in arriving at the claimed invention by combining the teachings of the cited references. Accordingly, reconsideration and withdrawal of this rejection are requested.

Related Applications

Applicants have previously made of record the following co-pending, commonly owned applications: application serial number 10/409,272; application serial number 11/207,334; application serial number 11/232,801; application serial number 11/168,620; and application serial number 11/473,934. Applicants are awaiting a first substantive action in application serial number 11/232,801. Substantive prosecution of application serial numbers 10/409,272, 11/168,620, 11/207,334, and 11/473,934 is ongoing and the Examiner is invited to consider any prior and/or ongoing prosecution. The most recent action in application serial number 10/409,272 is a non-final Office Action mailed September 30, 2008 (a response to which was filed November 21, 2008). The most recent action in application serial number 11/168,620 is a non-final Office Action mailed August 4, 2008 (a response to which was filed November 5, 2008). The most recent action in application serial number 11/207,334 is a non-final Office Action mailed October 15, 2008. The most recent action in application serial number 11/473,934 is a non-final Office Action mailed June 9, 2008 (a response to which was filed December 5, 2008).

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000.

Please charge any deficiency or credit any overpayment in the fees that may be due in this matter to **Deposit Account No. 18-1945**, from which the undersigned is authorized to draw, under **Order No. 103514-0011-103**.

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Respectfully submitted,

By _____

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